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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,079	01/14/2002	Meir Rosenberg	022719-0026	5373
21125	7590	09/09/2004	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/047,079		ROSENBERG ET AL.	
	Examiner		Art Unit	
	Leslie R. Deak		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 8-10, 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,141,502 to Macaluso, Jr. Macaluso discloses a catheter with a proximal and distal end an inner lumen that extends between the proximal and distal ends (see FIG 7, 9). The distal end may comprise a coil-shaped region with between one and ten coils, between one and forty fluid entry ports thereupon, and a distal fluid port. The catheter is comprised of two sections: a distal tube body 19 and a bladder coil 23 that are connected at hub 27, wherein the tube portions are formed of polymeric material that retains its shape in a coiled position (see FIG 7, column 2, lines 1-5). With regard to the claim limitations drawn to the method of forming the catheter, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. With regard to applicant's omission of ports in a particular portion of the device, it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. See MPEP 2144.04.

3. Claims 2-7, 11-13, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,141,502 to Macaluso, Jr. in view of US 6,595,966 to Davey et al and US 4,950,232 to Ruzicka et al. Macaluso discloses the apparatus as claimed with the exception of the shaped inlet ports, increasing diameter, and size limitations claimed by applicant. Davey discloses a catheter that utilizes a tapered shape that increases the diameter of the inner lumen from the distal end to the proximal end in order to maximize flow rate and reduce trauma to the fluid flowing therein (see columns 1-2). Davey further discloses that the principles of the tapered design of his catheter may be applied to a catheter design that is dimensioned according to the needs of its specific use (see column 8, lines 9-14). Furthermore, absent an indication as to the criticality of the claimed dimensions of the catheter and shapes and sizes of the inlet openings, it is considered an obvious matter of design choice, since applicant has not disclosed that the specific dimensions and shapes solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with generically suitable, lengths, and inlet port shapes. Furthermore, Ruzicka discloses and illustrates a catheter with a spiraled tip in which the diameter of the spiraled tip is substantially equal to the diameter of the catheter itself (see FIG 7). Ruzicka further discloses a stylet 72 used for insertion of the catheter. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the catheter disclosed by Macaluso with a tapered internal diameter and create the Macaluso catheter of an appropriate size for the desired operation in order to increase fluid flow through the catheter, provide an

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appropriately-dimensioned catheter, and provide a stylet in order to ease the catheter insertion procedure, as taught by Davey and Ruzica.

Response to Arguments

4. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

5. Omission of ports on a single side of a device does not render the instant invention patentable over the prior art of record. It has been held that the omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. See MPEP 2144.04.

6. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In particular, Examiner has combined the teachings of patents concerned with hollow drainage tube structures, as presently claimed by applicant. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying

the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Davey specifically contemplates and discloses that the design of his catheter may be altered to suit many different applications and uses. Such a disclosure is motivation to combine the Davey reference with another drainage catheter in order to create a prima facie case of obviousness.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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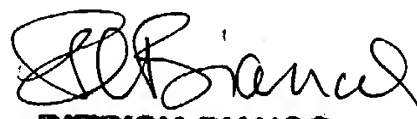
the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
30 August 2004


PATRICIA BIANCO
PRIMARY EXAMINER
9/7/04